

VAMHCS RESEARCH SERVICE HOT TOPIC

Vol. 6 No. 1
January 24, 2012

New VA Requirements for Separation of VA vs. Non-VA Activities in Research Projects with University Affiliates

In July 2011, VHA Office of Research Oversight (ORO) issued an “[Interim Guidance on Research Data Disclosures for ‘Collaborative’ Studies](#)”, followed by an “[Implementation Update](#)” on 12/12/11.

The purpose of the guidance was to clarify **current** requirements for the disclosure of VA research data to academic affiliates and other non-VA entities for “collaborative” human subject research. It replaces some prior ORO guidances and also intends to facilitate implementation of the principles articulated by the *Working Group on Information Technology Security and Privacy in VA and NIH-Sponsored Research* (Association of American Medical Colleges, November 2010).¹

“Collaborative studies with non-VA entities pose distinct challenges related to records retention, the disclosure of data under the Health Insurance Portability and Accountability Act (HIPAA), data ownership, and data security, each of which requires consideration relative to collaborative research arrangements”.

The main goal of these requirements is for research projects to clearly define what is done at or through the VA and what is done at or through our affiliated university. By defining studies in this way, it is expected that

- ownership of data and sharing agreements will be more clearly established,
- liability & compensation for participant injury will depend on the location/practitioner in which the injury occurs,
- research informed consent forms and HIPAA authorizations will be more informative to participants.

■ Effective immediately, the VAMHCS Research Service is phasing in these new requirements.

■ All VA projects created in CICERO as drafts after 2/29/12 will be required to complete applicable portions of the Research Service Investigator Tool, “[Template for Developing a ‘VA-UM Collaborative Protocol’](#)”.

■ The R&D Committee will not approve any VA protocols created in CICERO as drafts after 2/29/12 that have not satisfactorily addressed the “collaborative studies” issue.

¹ https://www.aamc.org/download/138118/data/va_report.pdf.pdf

- If you are an investigator with a dual appointment and you are conducting or plan to conduct research involving VA resources, you may have a “VA-UM Collaborative Study” and are therefore directly affected by these new requirements.
- Definitions:
 - Dual appointment: Investigator who is paid by both the UM and VA, or who is paid by the VA and has a WOC appointment to the VA. PI must have a fulltime UM academic appointment except for rare instances where an exception has been granted by the UM institutional official.
 - “VA-UM Collaborative Study”: A study in which research activities are conducted at **both VAMHCS** (at VA or VA-leased space, on VA time, using VA resources) **and UM** (at UM, on UM time, using UM resources).
 - VA Resources: VA funding (full or partial), VA staff (paid or WOC), PI time while on VA tour of duty, use of VA space or VA leased space, location of interactions in VA space or VA leased space, use of VA data, use of VA specimens or tissue banks, etc.
- The scenarios are as follows:
 - If your study is conducted entirely at the University, with no VA funding or use of VA resources, these requirements do not affect your study.
 - If your study is conducted entirely at the VA, with no use of University resources, these requirements do not affect your study. Proceed with IRB approval and R&D Committee (RDC) approval according to current procedures.
 - If your study is conducted at both VAMHCS (at VA or VA-leased space, on VA time, using VA resources) **and UM** (at UM, on UM time, using UM resources), you have “VA-UM Collaborative” research and the new requirements **DO APPLY** to your study.
 - Decide on whether you should design separate VA and UM studies whose data will be combined (as in a multi-center trial) or whether you will design an integrated study (similar to what is typically done now) in which VA activities and UM activities are clearly defined.
 - Decide whether the VAMHCS or the UM will be the “local data coordinating center”.
- The VAMHCS Research Service and VA Office of Research Oversight (ORO) has designed the following tools to guide you through the decision points and documentation required for “VA-UM Collaborative Studies”:
 - [Guidelines and Template for Developing a “VA-UM Collaborative Protocol”](#);
 - [Collaborative Study Decision Flowchart](#);
 - [VAMHCS Reviewer Guide for Separation of VA vs. Non-VA Research](#);
 - [VA ORO Suggested Activities table for VA vs. Non-VA Research](#);
 - VAMHCS Informed Consent Template (revision to be posted shortly; current version is adequate)
 - VAMHCS HIPAA Authorization Template (revision to be posted shortly; current version is adequate)

- Personal consultation with Research Service by appointment and as staffing allows
- Continuing Review:
 - Implementation of these new requirements for continuing review will be phased-in shortly. A Research Service Bulletin will be issued at that time.
 - For existing studies in which VA data has already been combined with non-VA data at the time of continuing review, you will need to describe where the combined data are located and you will need to amend informed consent forms and HIPAA authorizations to separate VA versus non-VA (i.e., affiliate) research.
- TIP: Start with the [Guidelines and Template for Developing a “VA-UM Collaborative Protocol”](#) and the [“Collaborative Study Decision Flowchart”](#) as a guide for this process. Use the additional aids and templates as applicable. If you have difficulty, contact the Research Service or R&D Committee for assistance.

For questions concerning this or other Research Service Hot Topics OR for adding staff or colleagues to the Hot Topics mailing list, contact:

Jessica Mendoza,
Human & Animal Research Protections Officer
Room 4D-185
410-605-7000 x6512
jessica.mendoza@va.gov

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http://www.maryland.research.va.gov/hot_topics.asp

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